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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,889	11/07/2001	Robert D. Black	9099-4	7939

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,889	BLACK, ROBERT D.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-17,29-31, 35-37 and 38-42* is/are pending in the application.

4a) Of the above claim(s) *38-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-17,29-31 and 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed December 9, 2005 is acknowledged and has been entered.

Rejections Withdrawn

The 112 2nd rejections of claims 8, 33 and 37 are withdrawn in view of applicant's amendments to the claims.

Further, Applicants amendment to the claims and the arguments that Kovacs and Crowley are not capable of releasing molecules is found persuasive and the 102 rejections of Kovacs and Crowley are thus withdrawn. However, the following rejections are made as follows.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 8, 15-17 and 29-31, 34, 36 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Santini, Jr. et al (US 6,551,838).

Santini, Jr. et al. disclose a circuit for in vivo applications. Santini, Jr. et al. disclose the circuit comprises a fiber optic which emits light (optical radiation source). Santini, Jr. et al also discloses that the fiber optic can detect and measures changes

(optical radiation detector) in fluorescence or some other optical phenomenon. Santini, Jr. et al disclose control circuitry coupled to the fiber optic (col 9, lines 54-67, col 15, line 59 – col 16, line 43 and Figure 7). Santini, Jr. et al disclose coating or encapsulating all components of the circuit in a biocompatible material such as polyethylene glycol or metal or ceramic (col 9, lines 47-51 and col 15, lines 47-51). Santini, Jr. et al disclose the circuit is on a backing plate (platform) (col 17). Santini, Jr. et al disclose the device can be the size of a millimeter (col 4, lines 35-36).

With respect to the recitation "optical radiation emitted by excited labeled binding molecules" as recited in the instant claims. Since Santini Jr., et al teach the same circuit as recited, the circuit of Santini Jr., is capable of detecting excited labeled binding molecules and therefore, Santini Jr., et al anticipates the claims.

With respect to the fluorescently labeled antibodies as recited in the instant claims. The fluorescently labeled antibodies are not part of the circuit and thus Santini Jr., et al reads on the instantly recited claims because Santini Jr. et al is capable of releasing fluorescently labeled antibodies.

With respect to the recitations "for in vivo use that emits first optical radiation", "for in vivo use that detects second optical radiation emitted by excited labeled binding molecules" and "and "configured to release", "configured to activate" and "configured to sense" these recitations are intended use of the circuit and a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention form

the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, Santini Jr. et al reads on the instantly recited claims.

With respect to 29-32, 34, 36 and 37 since Santini Jr. et al disclose the same structures as recited in the instant claims and since Applicant has not recited any structural differences over Santini Jr. et al. The circuit of Santini Jr. et al is capable of performing the limitations of the recited claims and therefore, Santini Jr. et al anticipates the claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini Jr. et al. (US 6,551,838) in view of Gazdzinski (US 2001/0051766) or Meyer et al (US 6,217,869).

See above for the teachings of Santini Jr. et al.

Santini Jr. et al differ from the instant invention in failing to specifically teach the optical radiation source comprises a laser.

Gazdzinski et al disclose a laser coupled to a fiber optic (page 14, paragraph 0177, Fig. 11). Gazdzinski et al disclose that this provides for the transmission of light energy in an efficient manner (paragraph 0177).

Meyer et al disclose a fiber optic coupled to a laser (col 49, lines 19-25). Meyer et al disclose that this provides for the precise delivery of light.

It would have been obvious to one of ordinary skill in the art to incorporate a laser as taught by Gazdzinski et al into the device of Santini Jr. et al because it is well known in the art to couple fiber optics with lasers and further because Gazdzinski et al shows that this provides for the transmission of light energy in an efficient manner.

It would have also been obvious to one of ordinary skill in the art to incorporate a laser as taught by Meyer et al into the device of Santini Jr. et al because it is well known in the art to couple fiber optics with lasers and further because Meyer teaches that this provides for the precise delivery of light.

6. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santini Jr. et al (US 6,551,838) in view of Crowley (US 6,119,031).

See above for the teachings of Santini Jr. et al.

Santini Jr. et al differ from the instant invention in failing to teach the optical radiation detector is photodiode. Santini Jr. et al also fails to specifically teach filters coupled to the radiation source and radiation detector.

Crowley teaches a circuit comprising a light source (optical radiation source) and a light detector (optical radiation detector). Crowley teaches that the light source illuminates a substance and the detectors detect optical properties of the illuminated substance by measuring modified light signals (col 2, lines 18-31) (Figure 1A). Crowley teaches the circuit comprises a modulator for modulating the light source and also comprises an analog to digital converter and a microprocessor for spectral analysis (col 3, lines 34-57). Crowley teaches the light source may be a light emitting diode and the light detector may be a photodiode (col 2, lines 44-50). Crowley teaches the light source may be coupled to a filter (col 9, lines 8-11). Crowley teaches the light detector may be coupled to a filter (col 5, lines 20-48, Fig. 2A and Fig. 4). Crowley teaches that this provides for a device which is less expensive and are less complex and advantageous of optical fibers (col 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a detector and filters as taught by Crowley into the method of Santini Jr. et al because Santini Jr. et al specifically teaches that a sensing component such as a light detecting component can be used with the device of Santini Jr. et al and further because Crowley teaches that this provides for a device which is less expensive and are less complex and advantageous of optical fibers.

With respect to the first frequency is greater than the second frequency as recited in the instant claims. This limitation depends on the label that is used, and the label is not part of the circuit and therefore, whether or not the first frequency is greater than the second frequency is irrelevant. Therefore, Santini Jr., et al and Crowley read on the instantly recited claims.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini Jr. et al in view of Sheppard, Jr. et al (US 2002/0072784).

See above for teachings of Santini Jr. et al.

Santini Jr. et al differ from the instant invention in failing to teach an inductor coupled to the processor (page 5, paragraph 0055 and Figure 1).

Sheppard Jr. et al. disclose an inductor coupled to a processor. Sheppard Jr. et al discloses that this inductor provides for devices, systems and methods for wirelessly powering and/or communicating with microchip devices used for the controlled exposure and release of reservoir contents (abstract). Sheppard Jr. et al also teaches that this provides for devices for reducing or eliminating the need for pre-charged power sources and provides avoiding explantation of implanted microchip devices for the purpose of replacing or recharging the devices power source or for the purpose of reprogramming the devices' microprocessor and also provides additional means for powering and communicating with microchip devices (page 1, paragraphs 0007-0009).

It would have been obvious to one or ordinary skill in the art at the time the invention was made to incorporate an inductor such as taught by Sheppard Jr. et al into the processor of Santini Jr. et al because Sheppard Jr. et al teaches that this inductor

provides for devices, systems and methods for wirelessly powering and/or communicating with microchip devices used for the controlled exposure and release of reservoir contents (same type of device as disclosed in Santini Jr. et al.) and further because Sheppard Jr. et al also teaches that this provides for devices for reducing or eliminating the need for pre-charged power sources and provides avoiding explantation of implanted microchip devices for the purpose of replacing or recharging the devices power source or for the purpose of reprogramming the devices' microprocessor and also provides additional means for powering and communicating with microchip devices.

8. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini, Jr. et al (US 6,551,838) in view of Santini Jr. et al (US 6,491,666).

See above for the teachings of Santini Jr. et al (US 6,551,838).

Santini Jr. et al (US 6,551,838) differs from the instant invention in failing to specifically teach a piezoelectric circuit responsive to the processor circuit, wherein the piezoelectric circuit is configured to vibrate under control of the processor circuit to release the labeled binding molecules.

Santini Jr. et al (US 6,491,666) disclose microfabricated devices for the release of molecules. Santini Jr. et al (US 6,491,666) disclose piezoelectric elements such as a thin film of piezoelectric material that form a barrier layer. Santini Jr. et al (US 6,491,666) disclose that actuation of this piezoelectric material is achieved by components located on the device that generate ultrasonic energy (col 12, lines 11-47). Therefore, Santini Jr. et al (US 6,491,666) disclose a piezoelectric circuit. Santini Jr. et

al (US 6,491,666) disclose that these components are activated by control circuitry (col 3). Santini Jr. et al (US 6,491,666) disclose that this provides for an alternative active release device (col 12) and also provides for accurate and reliable delivery of molecules (col 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate piezoelectric elements and components as taught by Santini Jr. et al (US 6,491,666) into the device of Santini Jr. et al (US 6,551,838) because Santini Jr. et al (US 6,551,838) specifically teaches that the barrier layer is responsive to a stimulus (col 8, lines 53-57) and Santini Jr. et al (US 6,491,666) teaches that this provides for disintegration of a barrier layer and also this provides for an alternative active release device which provides for accurate and reliable delivery of molecules. Therefore one of ordinary skill in the art would have a reasonable expectation of success incorporating piezoelectric elements and components as taught by Santini Jr. et al (US 6,491,666) into the device of Santini Jr. et al (US 6,551,838).

Response to Arguments

9. Applicant's arguments filed December 9, 2005 have been fully considered but they are not persuasive.

Applicant argues that Santini does not disclose, for example a processor circuit configured to release fluorescently labeled antibodies selected to bind with predetermined tumor specific antigens. This is not found persuasive be the fluorescent labeled antibodies are not a part of the circuit and are thus irrelevant. Further, the circuit of Santini is capable of releasing molecules from the device (see for example col

2, lines 41-51). Therefore, Santini is capable of releasing fluorescently labeled antibodies. Further, the limitations which applicant relies upon "configured to release fluorescently labeled antibodies selected to bind with predetermined tumor specific antigens" is intended use of the circuit and as stated above and in the previous office action a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention form the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, Santini Jr. et al reads on the instantly recited claims. Further, language such as "configured to" that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of the claim or claim limitation (MPEP 2106).

Applicant further argues that with respect to many dependent claims (i.e. 29-34, 36 and 37), the Official Action considers that Santini discloses the detailed recitations thereof without the explicit disclosure of the details recited therein. This is not found persuasive because the limitations are directed toward intend use of the circuit and since Santini Jr. et al teach the same structures as recited in the instant claims and since Applicant has not recited any structural differences over Santini Jr. et al. The circuit of Santini Jr. et al is capable of performing the limitations of the recited claims and therefore, Santini Jr. et al anticipates the claims.

Applicant further argues that claim 37 recites in-part that the "processor circuit is further configured to release the unlabeled binding antibodies during a time interval and

to release the fluorescently labeled antibodies during a second time interval". This is not found persuasive because the antibodies are not a part of the circuit and once again this is intended use of the circuit. Further, Santini Jr. et al is capable of releasing two different antibodies as two different times. The circuit and device of Santini are designed for the timed exposure of molecules (see for example, col 1, lines 47-49, col 2, lines 22-41, col 8, lines 14-67, col 9, line 32 – col 10, line 67) is capable of releasing any type of antibody. Thus since Santini Jr. et al teaches the same structures as recited in the instant claims and since Applicant has not recited any structural differences over Santini Jr. et al. The circuit of Santini Jr. et al is capable of performing the limitations of the recited claims and therefore, Santini Jr. et al anticipates the claims.

Conclusion

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
February 22, 2006

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